DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-1194]

Fresenius Kabi Deutschland GmbH; Withdrawal of Approval of New Drug Application of Hydroxyethyl Starch

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of a new drug application (NDA) BN 070012/0022 for VOLUVEN (6 Percent Hydroxyethyl Starch 130/0.4 in 0.9 Percent Sodium Chloride Injection), held by Fresenius Kabi Deutschland GmbH. Fresenius Kabi Deutschland GmbH requested in writing that the Agency's approval of the application be withdrawn because the drug is no longer being marketed and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

FOR FURTHER INFORMATION CONTACT: Myrna Hanna, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION: Fresenius Kabi Deutschland GmbH, Bad Homburg, Germany (Authorized U.S. Agent: Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047), has requested that FDA withdraw approval of NDA BN 070012 sequence 0022, pursuant to § 314.150(c) (21 CFR 314.150(c)), because the drug is no longer being marketed. By its request, Fresenius Kabi Deutschland GmbH, has also waived its opportunity for a hearing. Withdrawal of approval of an application under § 314.150(c) is without prejudice to refiling.

Application No.	Proprietary Name
NDA BN 070012/0022	VOLUVEN (6% Hydroxyethyl Starch 130/0.4 in 0.9% Sodium Chloride Injection)

Therefore, approval of the application listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Introduction or delivery for introduction into interstate commerce for products without a new drug application violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). The drug product that is listed in the table above that is in inventory on **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** may continue to be dispensed until the inventory has been depleted or the drug product has reached its expiration date or otherwise becomes violative, whichever occurs first.

Dated: December 3, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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